UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF KENTUCKY
AT LOUISVILLE

WILLIAM L. STEIDEN PLAINTIFF

v. CIVIL ACTION NO. 3:11CV-441-S

GENZYME BIOSURGERY, A DIVISION OF
GENZYME CORPORATION DEFENDANT

MEMORANDUM OPINION

On July 6, 2011, William L. Steiden filed suit in the Jefferson Circuit Court against Genzyme Biosurgery, a Division of Genzyme Corporation,[1] the manufacturer and seller of Synvisc-One®, a Class III medical device. The Complaint alleges that Synvisc-One® is an unreasonably dangerous product that caused him injury.

Steiden has bilateral degenerative arthritis in his knees. He was treated by an orthopedic surgeon on July 22, 2010 for this condition. The complaint alleges that the physician injected Synvisc-One® into Steiden's knees and that he immediately suffered an adverse reaction in the right knee. Steiden allegedly suffered serious injury as a result of this occurrence.

Genzyme removed the action to this court under our diversity jurisdiction, alleging that Steiden is a Kentucky resident, Genzyme is a Massachusetts corporation with its principal place of business in Massachusetts, and the amount in controversy in this action exceeds $75,000.00. Compl., ¶¶ 3; 4. Genzyme has now moved to dismiss the action on the ground that the Complaint

[1]The defendant states that it should be referred to simply as Genzyme Corporation. The plaintiff also makes reference in the complaint to "Ho Sports" and "Heather Kininmonth." These appear to be editing errors.

as well as the proposed Amended Complaint fail to state a claim upon which relief may be granted. Fed.R.Civ.P. 12(b)(6).

Genzyme contends that Steiden's strict liability product defect claim is preempted by the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Acts, 21 U.S.C. § 360k(a)("MDA") which provides, in pertinent part:

> ...[N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement...which is different from, or in addition to, any requirement applicable under this chapter to the device, and ...which relates to the safety or effectiveness of the device or to any other matter included in the requirement applicable to the device under this chapter.

The MDA provides a "detailed regime of federal oversight" (*Riegel v. Medtronic, Inc.*, 128 S.Ct. 999, 1003 (2008)) in the premarket evaluation and approval process used to assess the "safety and effectiveness of medical devices intended for human use." (*White v. Stryker Corp.*, 818 F.Supp.2d 1032, 1034 (W.D.Ky. 2011)). Once the FDA has approved a medical device through the premarket approval ("PMA") process, a PMA approval order is issued, delineating standards with which the applicant must comply in the manufacturing, marketing and sale of the approved device. 21 CFR § 814.80. The FDA also requires the submission of Adverse Reaction Reports and Device Defect Reports documenting any safety and maintenance issues with the device. 21 CFR § 814.84.

> The PMA process is "a rigorous one." ***Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477, 116 S.Ct. 2240, 135 L.Ed.2d 700 (1996)**. "Manufacturers must submit detailed information regarding the safety and efficacy of their devices, which the FDA then reviews, spending an average of 1,200 hours on each submission." ***Id.*** When analyzing that information, the FDA must weigh the "probable benefit to health from the use of the device against any probable risk of injury or illness from such use." **21 U.S.C. § 360c(a)(2)(C)**. Accordingly, the FDA sometimes grants PMA to potentially life-threatening devices, if they "offer great benefits in light of available alternatives." ***Riegel*, 128 S.Ct. at 1004;** *accord* ***Heisner ex rel. Heisner v. Genzyme Corp.*, No. 08–C–593, 2008 WL 2940811, at *5 (N.D.Ill. July 25, 2008)** ("Out of practical necessity and the cold calculus of nationwide regulation, the FDA may be aware of a certain failure rate associated with a

> medical product and yet approve it."). The PMA process also requires the FDA to review a device's proposed labeling to ensure that it is neither false nor misleading. *See* **21 U.S.C. § 360c(a)(2)(B)**.

In re Medtronic, Inc. v. Sprint Fidelis Leads Prod. Liab. Litig., 592 F.Supp.2d 1147, 1150 (D.Minn. 2009).

The United States Supreme Court has held that under § 360k(a) most common law tort duties are preempted by the MDA with respect to pre-approved medical devices. *See Riegel, supra.* Steiden does not dispute that the product liability claim which forms the basis of his original complaint is preempted by the MDA. Instead, Steiden seeks leave to file an Amended Complaint.

Steiden seeks to add allegations that:

(1) Genzyme failed to comply with the FDA's premarket approval requirements in the continued manufacture, distribution and sale of Synvisc-One®;

(2) Genzyme manufactured, held, sold, and delivered an adulterated dose of Synvisc-One®;

(3) Genzyme did not meet the FDA's Current Good Manufacturing Practices ("CGMPs") in the manufacture, distribution and sale of Synvisc-One®; and

(4) Genzyme violated KRS 217.175 by manufacturing, holding, selling and delivering an adulterated dose of Synvisc-One®, the violation of which constitutes negligence *per se*.

Genzyme urges the court to deny the motion for leave to amend on the ground that amendment would be futile. Genzyme contends that the proposed Amended Complaint lacks the factual specificity to state a plausible claim under *Iqbal* and *Twombly* that is not preempted by the MDA.

The Amended Complaint does not incorporate any new factual allegations. Paragraph 4 of the original complaint contains the sum total of facts offered at this point: "William L. Steiden, a patient of Dr. Edward Tillett, an orthopedic surgeon who practices in Jefferson County, Kentucky, had both of his knees injected with Synvisc-One® (HYLAN G-F 20) on July 22, 2010. The plaintiff suffered an immediate adverse reaction after the injection of Synvisc-One® (HYLAN G-F 20) in his right knee." Genzyme asserts that the proposed Amended Complaint (1) fails to meet the pleading standards of *Ashcroft v. Iqbal*, 129 S.Ct. 1937 (2009) and *Bell Atlantic Corp. v. Twombly*, 127 S.Ct. 1955 (2007), and (2) fails to fit within the narrow window of allegations that survive federal preemption.

Genzyme would have the court adopt the reasoning set out in *White v. Stryker Corp.*, 818 F.Supp.2d 1032 (W.D.Ky. 2011), and find the allegations of Steiden's proposed Amended Complaint deficient.[2]

In *White*, the plaintiff underwent a total hip arthroplasty in which a medical device known as the Trident System was implanted. More than five years after the surgery, the plaintiff had a second surgery during which the physician allegedly discovered that certain components of the Trident system had "failed." The plaintiff alleged that "defendants failed to manufacture [the Trident System] according to FDA approved standards and procedures for medical devices." *Id.* at 1033. The court found that the complaint did not contain sufficient specificity to meet the requirements of *Iqbal* and *Twombly*. The court noted that the "Amended Complaint neither cites

[2]We note that in *White* the court had already granted leave to amend. The issue addressed was whether sufficient facts had been plead to state a plausible claim for relief which was not preempted by the MDA. We address the same issue, both in the context of Genzyme's arguments of futility and failure to state a claim for relief.

any particular federal standard or procedure, nor does it generally state how the alleged defect deviated from the federal standard or procedure." *Id.*

The court discussed the current cases addressing PMA preemption. It dismissed the Amended Complaint as insufficient to state a plausible claim for relief, noting that

> Plaintiff has not alleged any specific manufacturing failure, has not alleged the violation of any specific federal standard, including GMPs, and has already amended his complaint once in response to the motion to dismiss...It does not identify any particular design flaw, manufacturing impropriety or product defect. It does not assert either a PMA-specific standard or a GMP regulation, the violation of which might form the basis for a state law action.

Id. at 1039.

We find that the facts before this court mandate a different result from that reached in *White*. For the reasons articulated below, we find that Steiden's proposed Amended Complaint contains sufficient facts to support a plausible claim for relief which is not preempted by the MDA. The case of *Bausch v. Stryker Corp.*, 630 F.3d 546 (7th Cir. 2010), cited but not followed in *White*, informs our decision.

The *Bausch* case involved the same Trident System which was at issue in *White*. However, unlike White, Bausch alleged that the Trident System was adulterated, citing to an FDA warning letter which indicated that the Trident System was "adulterated due to manufacturing methods...not in conformity with industry and regulatory standards." *Id.* at 559. The court found that Bausch's allegations were sufficient to survive an *Iqbal/Twombly* challenge, as the complaint "served the purposes of Rule 8 of giving the defendants fair notice of the nature of the claim against them and of stating a claim for relief that was "plausible on its face" as required by *Iqbal* and *Twombly*...'As a general rule...notice pleading remains the standard.'" *Id.* (internal citation omitted).

> The federal standard of notice pleading applies, so long as the plaintiff alleges facts sufficient to meet the new "plausibility" standard applied in *Iqbal* and *Twombly*...A

> claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged. [citation omitted]. In applying that standard to claims for defective manufacture of a medical device in violation of federal law, moreover, district courts must keep in mind that much of the product-specific information about manufacturing needed to investigate such a claim fully is kept confidential by federal law. Formal discovery is necessary before a plaintiff can fairly be expected to provide a detailed statement of the specific bases for her claim. Accordingly, the district court erred in this case by dismissing plaintiff's original complaint and by denying her leave to amend her complaint.

Bausch, 630 F.3d at 558. The court found that although the original complaint did not specify the precise defect or the specific federal regulatory requirements that were allegedly violated, the absence of those details did not provide a valid basis for dismissal under Rule 12(b)(6). *Id.* at 560.

The *Bausch* court cited the unpublished Sixth Circuit opinion, *Howard v. Sulzer Orthopedics*,[3] in concluding that it was not necessary to show violation of a device-specific requirement, as a claim based on an alleged violation of the Current Good Manufacturing Practices could avoid preemption. The court reasoned:

> Like the Sixth Circuit in ***Howard,*** we do not see a sound legal basis for defendants' proposal to distinguish between general requirements and "concrete, device-specific" requirements. **Section 360k** makes preemption a defense if a state seeks to impose on a manufacturer "any requirement—(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter." **21 U.S.C. § 360k(a)**. We emphasize the phrase "any requirement." And federal law is clear: for manufacturers of Class III medical devices, the Quality System Regulations and Current Good Manufacturing Practices adopted by the FDA under its delegated regulatory authority are legally binding requirements "under this chapter." **21 C.F.R. § 820.1**. "The failure to comply with any applicable provision in this part [of the regulations] renders a device adulterated under section 501(h) of the act. Such a device, as well as any person responsible for the failure to comply, is subject to regulatory action." **21 C.F.R. § 820.1(c)**.

[3] 382 Fed.Appx., 2010 WL 2545586 (6th Cir. June 16, 2010).

> Defendants' proposed distinction between concrete, product-specific requirements and more general requirements would also leave injured patients without any remedy for a wide range of harmful violations of federal law. The FDA regulations contain many requirements that are not concrete or product-specific, yet which are obviously vital to producing safe and effective medical devices. For example, the regulations require each manufacturer to "establish and maintain procedures to prevent contamination of equipment or product by substances that could reasonably be expected to have an adverse effect on product quality," **21 C.F.R. § 820.70(e)**, and to "establish and maintain procedures for the use and removal" of manufacturing material (such as lubricants or abrasives, or cleaning and disinfectant agents) "to ensure that it is removed or limited to an amount that does not adversely affect the device's quality." **21 C.F.R. § 820.70(h)**. If a patient were harmed by an implanted hip replacement system that was contaminated, for example, by a production worker's blood or mucus or by a lubricant or abrasive that caused an infection after implantation, that contamination would present a substantial claim for violating requirements that are not "concrete" and "product-specific," yet which surely are essential for the manufacture of safe and effective medical devices for implantation in the human body. See ***Howard*, 382 Fed.Appx. at 442** (reversing summary judgment for manufacturer when lubricant used in manufacturing had been left on knee replacement implanted in plaintiff).

Genzyme takes issue with the paucity of facts alleged by Steiden and urges that he has failed to provide sufficient specificity to elevate a claim of possibility to a claim of probability, as required to meet the *Iqbal/Twombly* standard. There are indeed precious few facts alleged. However, the facts appear to be fairly simple and straightforward. It is claimed that on a particular date, both of Steiden's knees were injected with Synvisc-One®, and he allegedly suffered an immediate adverse reaction in one of them. He claims that the product was adulterated, that Genzyme violated federal CGMPs, the PMA for the device, and state law prohibiting the manufacture and sale of adulterated medical devices.

We find the factual allegations before us indistinguishable from those in *Bausch* where the plaintiff cited to the above-referenced FDA letter stating that the device was "adulterated." Nothing more specific was required in *Bausch* to state a plausible claim for adulteration. Similarly, we find

that the allegation of adulteration based on the occurrence of an immediate adverse reaction in one knee to the injection of Synvisc-One® contains sufficient specificity to satisfy *Iqbal* and *Twombly*.

In *White*, the plaintiff did not allege any specific manufacturing failure or violation of any federal standard. He alleged general claims of product liability, negligence and warranty. 818 F.Supp.2d at 1039. By contrast, Steiden has alleged that the means by which he was injured was the injection into his knee of an adulterated dose of Synvisc-One®. He claims that CGMPs, the PMA and state law were violated thereby. As stated in *Riegel*, 128 S.Ct. at 1011,

> State requirements are pre-empted under the MDA only to the extent that they are "different from, or in addition to" the requirements imposed by federal law. **§ 360k(a)(1)**. Thus, **§ 360k** does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case "parallel," rather than add to, federal requirements. ***Lohr*, 518 U.S., at 495, 116 S.Ct. 2240;** see also ***id.*, at 513, 116 S.Ct. 2240** (O'Connor, J., concurring in part and dissenting in part).

For the foregoing reasons, the court will grant the motion for leave to amend the complaint to assert claims based upon a theory of adulteration of the device. The court will grant the motion to dismiss as to the product liability claim, but will deny the motion in all other respects. A separate order will be entered this date in accordance with this opinion.

IT IS SO ORDERED.

July 17, 2012

Charles R. Simpson III, Judge
United States District Court